K121158

II. SUMMARY AND CERTIFICATION

A. 510(k) Summary

AUG 6 2012

Submitter: Sterilmed, Inc.

Contact Person: Jason Skramsted
11400 73rd Avenue North
Maple Grove, MN 55369
Phone: 763-488-3483
Fax: 763-488-4491

Date Prepared: 13 April 2012

Trade Name: Reprocessed Electrophysiology Diagnostic Catheters

Classification Name: Electrode Recording Catheter or Electrode Recording Probe

Classification Number: Class II, 21 CFR 870.1220

Product Code: NLH

Predicate Devices:	The reprocessed EP diagnostic catheters are substantially equivalent to the Biosense Webster Coronary Sinus Catheters with EZ Steer Technology (K101345).
Device Description:	The EP diagnostic catheters are steerable, multi-electrode catheters with a deflectable tip designed to facilitate electrophysiological mapping of the heart. The catheters have a high-torque shaft with a braided bi-directional deflectable tip section containing an array of ten platinum electrodes that includes a 2 mm tip dome, which can be used for stimulation and recording. The catheters are 7 french with a usable length of 115 cm. The rocker lever located on the hand piece is used to deflect the tip section. A friction control knob is located on the opposite side of the rocker lever and can be rotated clockwise to lock both the tip curve and rocker lever in place. The high-torque shaft allows the plane of the curved tip to rotate, enabling accurate positioning of the catheter tip.
Intended Use:	The reprocessed EP diagnostic catheters are intended for temporary use during electrophysiology studies for intracardiac sensing, recording, and pacing for the electrophysiological mapping and evaluation of cardiac structures and arrhythmias.
Technological Characteristics:	The reprocessed EP diagnostic catheters are identical to the predicate devices in design, materials of construction, and intended use. There are no changes to the clinical applications, patient population, performance specifications, or method of operation.
Functional and Safety Testing:	Representative samples of reprocessed EP diagnostic catheters were tested to demonstrate appropriate functional characteristics. Process validation testing was performed to validate the cleaning and sterilization procedures as well as device packaging. In addition, the manufacturing process includes visual and validated functional testing of 100% of products reprocessed.
Summary of Non-clinical Tests Conducted:	Specific non-clinical tests performed included: cleaning validation, sterilization validation (ISO 11135, USP <71>), biocompatibility testing (ISO 10993-1), ethylene oxide residual testing (ISO 10993-7), packaging validation (ASTM D 4169, ASTM F 88, ASTM F 2096), and shelf life validation (ASTM F 1980). In addition, validation of functional performance (bench testing) was performed through simulated use, visual inspection, fatigue testing, and function testing. Performance testing shows the reprocessed EP diagnostic catheters to perform as originally intended.
Conclusion:	Sterilmed concludes that the reprocessed EP diagnostic catheters are safe, effective, and substantially equivalent to the predicate devices, Biosense Webster Coronary Sinus Catheters with EZ Steer Technology (K101345), as described in this premarket notification submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 6 2012

Sterilmed, Inc.
c/o Mr. Jason Skramsted
11400 73rd Avenue North
Maple Grove, MN 55369

Re: K121158
Trade Name: Reprocessed Electrophysiology Diagnostic Catheters
(4 models manufactured by Biosense Webster: BD7lOFJ282RTS, BD710DF282RTS, BD710FJ282CT, BD710DF282CT)

Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II (two)
Product Codes: NLH
Dated: July 18, 2012
Received: July 19, 2012

Dear Mr. Skramsted:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121158

Indications for Use

510(k) Number (if known): K121158

Device Name: Reprocessed Electrophysiology Diagnostic Catheters

Indications for Use: The reprocessed EP diagnostic catheters are intended for temporary use during electrophysiology studies for intracardiac sensing, recording, and pacing for the electrophysiological mapping and evaluation of cardiac structures and arrhythmias.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121158